

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Smith, RL et al  
Group/Art Unit: 1616

Application No.: 10/616,047 Filed: 7-7-2003  
Docket No. 0723 Examiner: J. Pak

Title: Stable Hydrogen Peroxide Compositions, Products and Methods of Use

Date: May 16, 2005

**APPENDIX OF EXPLANATORY PAPERS  
FOR ABOVE-CITED OFFICE ACTION**

Respectfully submitted,

Lori M. Friedman  
Reg. No. 35,143  
Customer Number 21837

## GPnotebook



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## demulcents

Demulcents are compounds which contain soothing substances, for example syrup or glycerol, which are claimed to reduce the symptoms in dry, irritating coughs.

Indeed they have this activity in some patients, but whether this is a placebo effect is a matter for debate.

### [Click here for more information...](#)

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What is 10 times sweeter than sugar,  
all natural, and has no calories?


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## Demulcent

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### Health Conditions

Abscess  
Acne  
ADD  
Addictions  
Aggressive Behavior  
Aging

### Key Health Centers

Alternative Medicine  
Cancer  
Clinic  
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Fitness  
Health Conditions

Information  
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### Alter. Therapies

Acupuncture  
Aromatherapy  
Ayurvedic Medicine  
Biofeedback Training  
Chelation Therapy  
Chinese Medicine

### Product Categories

Adaptogens  
Addictions  
Allergy  
Alternative Medicine  
Anger  
Anti-Aging  
Antioxidants  
Anxiety

**Could I have  
diabetes?**  
What are the tell-

A demulcent herbs have the effect of acting as a protective barrier on irritated or inflamed tissue. When they are used on the skin demulcents are called emollients. The experience of demulgency cannot always be explained pharmacologically. They contain complex polysaccharide molecules of mucilage, having the property of becoming slimy and gummy when in contact with water. This has a direct action on the lining of the intestines, soothing and reducing irritation by direct contact. However, there are some remedies that have a similar action far from the sight of absorption into the body, meaning that they cannot have such a direct action on, say, the urinary system, because the mucilage will have been broken down into its constituent parts losing its unique soothing action.

### Demulcents have these general properties:

- They reduce irritation down the whole length of the bowel.
- They reduce the sensitivity of the digestive system to gastric acids.
- Help to ease the digestive muscle spasms which cause colic.

### Some demulcents also:

- Ease coughing by a soothing of bronchial tension.
- Relax painful spasm in the bladder and urinary system, and sometime seven in the uterus.

### Herbal Demulcents

Coltsfoot  
Comfrey  
Corn Silk  
Couch Grass  
Flaxseed  
Iceland moss  
Irish Moss  
Liquorice  
Lungwort  
Marshmallow  
Mullein  
Slippery Elm

**Demulcents that are also Anti-Catarrhal :** Coltsfoot, Lungwort, Mullein

**Demulcents that are also Anti-Inflammatory :** Coltsfoot, Comfrey, Liquorice, Lungwort, Marshmallow, Mullein, Slippery Elm

**Demulcents that are also Anti-Microbial :** Couch Grass



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**Demulcents that are also Anti-Spasmodic :** Coltsfoot, Liquorice, Lungwort, Mullein

**Demulcents that are also Astringent :** Coltsfoot, Comfrey, Lungwort, Marshmallow, Slippery Elm

**Demulcents that are also Carminative :**

**Demulcents that are also Cholagogue :**

**Demulcents that are also Diaphoretic :** Mullein

**Demulcents that are also Diuretic :** Coltsfoot, Corn Silk, Couch Grass, Marshmallow, Mullein

**Demulcents that are also Emmenagogue :**

**Demulcents that are also Expectorant :** Coltsfoot, Comfrey, Irish Moss, Liquorice, Lungwort, Mullein

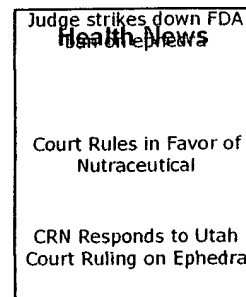
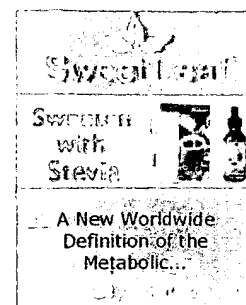
**Demulcents that are also Hepatic :**

**Demulcents that are also Laxative :** Flaxseed, Liquorice

**Demulcents that are also Nervine :**

**Demulcents that are also Tonic :** Coltsfoot, Corn Silk, Liquorice, Mullein

**Demulcents that are also Vulnerary :** Coltsfoot, Comfrey, Lungwort, Marshmallow, Mullein



### Featured Products

[...more products](#)



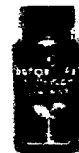
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## News Flash

**Petrolatum - Impurities in Petroleum Jelly or commonly known as Vaseline, under suspicion as a carcinogen in Breast Cancer - Petrolatum Banned in products in the EU - Long term damage to health becoming evident - side effects from impurities in the manufacturing process implicated in causing cancer!**

Read [Impurities of Concern in Personal Care Products](#)

"E-mail to a friend" 

<http://www.ewg.org/reports/skindeep/report/impurities.php>

**Breast cancer and impurities.** EWG's assessment of product ingredient labels and data on cancer-causing chemicals identified three common impurities in personal care products that are linked to mammary tumors in animal studies — ethylene oxide, PAHs, and 1,3-butadiene.

**The ingredients for which these impurities are of concern are used in one of every four personal care products on the market ([Table 4](#)).**

**Among girls born today, one in eight is expected to get breast cancer and one in 30 is expected to die from it (NCI 1996, 1997, 2000).** A review by scientists from Lawrence Berkeley National Laboratory shows that as many as one of every five chemical carcinogens causes mammary tumors in laboratory studies, indicating that the breast is more sensitive to carcinogens than almost any other tissue in the body (Gold et al. 1991). EWG's identification of three impurities linked to breast cancer does not represent a full accounting of possible mammary carcinogens in personal care products. Instead, it is a partial accounting based on the National Toxicology Program's assessment of mammary carcinogens (NTP 2000) and other sources in the peer-reviewed literature. **Further study would likely identify additional ingredients in personal care products that raise concerns with respect to breast cancer.**

**PAHs.** PAHs, or polycyclic aromatic hydrocarbons, are common contaminants in petrolatum, also called petroleum jelly and sold under well-known brand names like **Vaseline**. Petrolatum is found in one of every 14 products on the market (7.1 percent of the products assessed by EWG), including 15 percent of all lipstick and 40 percent of all baby lotions and oils. FDA restricts petrolatum in food to no more than 10 parts per million, and requires petrolatum used in food packaging or drugs to meet impurity restrictions for PAHs (21 CFR 178, 21 CFR 172.880).

**But the agency allows any amount of petrolatum of any purity in personal care products, many of which are applied directly to the lips and swallowed.**

**Manufacturers would find no legal impediments to using the same unregulated petrolatum in personal care products as can be used in shoe polish.**

Among the studies linking the petrolatum impurity PAHs to breast cancer is a Columbia University study in which researchers found that the breast tissue of women with breast cancer was 2.6 times more likely to contain elevated levels of PAHs bound to DNA (called DNA adducts) than the breast tissue of women without breast cancer (Rundle et al. 2000). The National Toxicology Programs finds that some PAHs are reasonable anticipated to be human carcinogens, and the State of California lists a number of PAHs as carcinogens in its Proposition 65 program (NTP 2002, OEHHA 2004).

**Petrolatum is listed as a probable human carcinogen in the European Union's Dangerous Substances Directive (UNECE 2004), and its use in cosmetics will be banned by September 2004 with the following caveat:**

**“The classification as a carcinogen need not apply if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen.”**

Chemical industry sources have interpreted this clause to mean that petrolatum will continue to be allowed in cosmetics in the EU if it is refined and meets PAH purity standards for food set by FDA (Faust and Casserly 2003). Even this purity standard does not set direct limits on PAH content, but instead relies on a light absorption test as an indirect indicator of contamination.

In the U.S. no requirement for refinement applies for petrolatum in personal care products. Some manufacturers likely choose refined petrolatum low in PAHs, but perhaps some do not.

**Product labels do not uniformly show the "USP" certification on the petrolatum listing in EWG's ingredient label database, and in any event, the certification criteria for a USP listing are not public.**

Some product labels include the term "skin protectant" in parentheses after the petrolatum listing, an indication that the petrolatum has been refined and meets FDA requirements for drug applications.

**But in most cases a consumer buying a product containing petrolatum has no way to know if the ingredient is low in carcinogenic PAHs or not.**

Read the full report on the EWA website. [CLICK HERE](#)

#### **Health-Report Comment:**

**Well folks, it never stops does it?**

**How many of you would ever have thought, a ubiquitous substance such as good ol' Petroleum Jelly or Vaseline as so many of us have come to call it over the last 50 years, is now a suspected and probable carcinogen because of the way it is manufactured?. Contaminants from petrolatum are being found in most breast cancer tissues which have been studied in recent times.**

**You know, I keep beating the same drum about these so called safe chemicals! Just because we have become used to using synthetic chemicals on the skin, it doesn't mean to say they have been beneficial in the long run to our health. FAR FROM IT! In fact, some of these toxic chemicals, may well have contributed to the cancer, a friend or loved one of yours, contracted and died from, in recent times.**

**Yes we all know people, loved ones and friends who have been cut down by this cancer scourge.**

**Every single one of us in Westernized society, knows someone who has died of cancer in the last 12 months. It's a frightening and awful reality, that the rate we contract cancer, is approaching 1 in every 2 people and will probably exceed this rate within twenty years!**

**It's only YOU who can do something about it by educating people you know to the dangers and by voting NO to chemicals simply by reading the labels! If the label has words**

on it you can't pronounce, then put it back on the shelf and don't run the risk of doing long term damage to your own health. You need to start explaining to people you know about reading labels and keeping the toxic chemicals out of their system.

You can actually be paid to do this if you join the Organic Movement and promote safe non toxic products like we do here at the Health-Report website.

**CERTIFIED ORGANIC** is the only guarantee you have of being chemical free. If you support the organic industry then you will not only be healthier and happier but you are also helping to save the planet from an impending disaster!

You have one life - live it safely by avoiding chemicals!

Geoff Goldie  
[www.health-report.co.uk](http://www.health-report.co.uk)

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# Skin Deep

A safety assessment of ingredients in personal care products



[Report Home](#) >> [About the Chemicals](#) >> **Petrolatum**

## Petrolatum

### Areas of Health Concern

<a href="#">Cancer</a>	<a href="#">Pregnancy Concern</a>	<a href="#">Safety Violation</a>	<a href="#">Harmful Impurities</a>	<a href="#">Penetration Enhancer</a>	<a href="#">Unassessed Ingredient*</a>	<a href="#">Allergen &amp; Other Health Concerns</a>
			✓			

### Explanation of Score

#### Health Concern

May be contaminated with impurities linked to cancer or other significant health problems

### Impurity Concerns

May contain harmful impurities: PAHs. []

### Government & Industry Toxicity Category Explanation

### Product Categories with Petrolatum

Petrolatum is found in 535 product(s) in our database.

Product Category	Products Count
<a href="#">Moisturizer</a>	106
<a href="#">Lip Makeup</a>	105
<a href="#">Lip Balm/Treatment</a>	48
<a href="#">Foundation</a>	36
<a href="#">Concealer</a>	28
<a href="#">Eye Makeup</a>	23
<a href="#">Baby Lotion/Oil</a>	21

<u>Styling Product</u>	19
<u>Facial Moisturizer/Treatment</u>	16
<u>Anti-Aging Treatment</u>	15
<u>Anti-Itch/Rash Cream</u>	11
<u>Body Wash/Cleansers</u>	11
<u>Blush</u>	10
<u>Foot Odor/Cream/Treatment</u>	9
<u>Bar Soap</u>	9
<u>Eye/Contact Care Product</u>	7
<u>Sunscreen/Tanning Oil</u>	7
<u>Shaving Products</u>	7
<u>Acne Treatment/Medication</u>	4
<u>Depilatory Cream/Hair Remover</u>	4
<u>Eye Treatment</u>	4
<u>Conditioner</u>	3
<u>Facial Cleanser</u>	3
<u>Nail Treatments</u>	3
<u>Antiperspirant/Deodorant</u>	3
<u>Exfoliator</u>	2
<u>Powder</u>	2
<u>Pain Relief Rub/Ointment</u>	2
<u>Liquid Hand Soap</u>	2
<u>Makeup Remover</u>	1
<u>Other Skin Treatment</u>	1
<u>Body Spray</u>	1
<u>Menopause Cream</u>	1
<u>Body Oils</u>	1
<u>Deodorant</u>	1

### Listed on Packages As

Petrolatum  
 Petrolatum (53.4%)  
 Petrolatum (53.4% - Skin Protectant)  
 Petrolatum (1%)  
 Petrolatum 30%  
 Petrolatum (44 %)  
 Petrolatum (41%)  
 Paraffin Jelly  
 Petrolatum 33% (skin protectant)  
 Petrolatum 56.8%  
 in Elta Base: Petrolatum  
 Petrolatum (43.0% Skin Protectant)  
 Petrolatum (U.S.P.)

Petrolatum (w/w) 49.5%  
Petrolatum (Petrolato)

## References

[UNECE, 2004; EU Directive 67/548/EEC]: United Nations Economic Commission for Europe (UNECE) (2004). The Globally Harmonized System of Classification and Labelling of Chemicals (GHS). <http://www.unece.org/trans/danger/publi/ghs/officialtext.html>. (Part 3: Health and Environmental Hazards);

[CIR 2003]: Cosmetics Ingredient Review (CIR) (2003). 2003 CIR Compendium, containing abstracts, discussions, and conclusions of CIR cosmetic ingredient safety assessments. Washington DC.

\* Ingredient(s) has/have not been assessed for safety by the cosmetic industry safety panel (the Cosmetic Ingredient Review, or CIR, panel) or by the federal government, with respect to use in cosmetics. Generally, ingredients not yet assessed for safety in cosmetics encompass a broad range of uses and toxicities - some are approved food additives while others are industrial chemicals linked to cancer. Some are generally known to be safe; others are linked to serious health concerns. More than 9,000 cosmetic ingredients have not been assessed for safety with respect to their use in these products.

[return to the previous page](#)

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[Contact Us](#)

Information from Google search of "calamine" 4-8-05

## Proper Use of This Medicine

Calamine is for external use only. Do not swallow it and do not use it on the eyes or mucous membranes such as the inside of the mouth, nose, genital (sex organs), or anal areas.

To use *calamine lotion*:

- Shake the lotion well before using.
- Moisten a pledget of cotton with the lotion.
- Use the moistened pledget to apply the lotion to the affected skin area(s).
- Allow the medicine to dry on the skin.

To use *calamine ointment*:

- Apply enough medicine to cover affected skin area(s) and rub in gently.

## Dosing—

*Follow your doctor's orders or the directions on the label.* The following information includes only the average dose of calamine. *If your dose is different, do not change it unless your doctor tells you to do so.*

- For minor skin irritations:
  - For *topical* dosage forms (lotion, ointment):
    - Adults and children—Apply to the affected area(s) of skin as often as needed.

## Storage—

To store this medicine:

- Keep out of the reach of children.
- Store away from heat and direct light.
- Keep the medicine from freezing. Do not refrigerate.
- Do not keep outdated medicine or medicine no longer needed. Be sure that any discarded medicine is out of the reach of children.

## Precautions While Using This Medicine

If your condition gets worse or if it does not improve within 7 days, or if rash or irritation develops, stop using calamine and check with your doctor.

## Side Effects of This Medicine

## Safety (MSDS) data for dimethicone



### General

Synonyms: silicone rubber, silicone latex, latex, dimethyl silicone, simethicone, dimethyl polysiloxane, dermafilm, silbar, dimethicream, poly(dimethylsiloxane), methyl silicone, dimethicone 350, good-rite, gum, hycar, poly(oxy(dimethylsilylene))

Use:

Molecular formula:  $[-\text{Si}(\text{CH}_3)_2\text{O-}]_n$

CAS No: 9016-00-6

EINECS No:

### Physical data

Appearance: colourless liquid with a viscosity which depends upon the extent of polymerisation

Melting point:

Boiling point:

Vapour density:

Vapour pressure:

Density ( $\text{g cm}^{-3}$ ):

Flash point:

Explosion limits:

Autoignition temperature:

Water solubility:

### Stability

Stable. Flammable or combustible. Flammability depends upon extent of polymerisation.

Incompatible with strong oxidizing agents.

### Toxicology

May act as an irritant.

**Toxicity data**

(The meaning of any toxicological abbreviations which appear in this section is given [here](#).)

**Risk phrases**

(The meaning of any risk phrases which appear in this section is given [here](#).)

## **Transport information**

(The meaning of any UN hazard codes which appear in this section is given [here](#).)

## **Personal protection**

Minimize exposure.

**Safety phrases**

Keep away from sources of ignition.

[Return to [Physical & Theoretical Chemistry Lab. Safety home page](#).]

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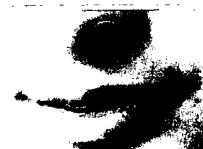
This information was last updated on December 28, 2002. We have tried to make it as accurate and useful as possible, but can take no responsibility for its use, misuse, or accuracy. We have not verified this information, and cannot guarantee that it is up-to-date.

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# Skin Deep

A safety assessment of ingredients in personal care products



[Report Home](#) >> [About the Chemicals](#) >> **Dimethicone**

## Dimethicone

### Areas of Health Concern

<a href="#">Cancer</a>	<a href="#">Pregnancy Concern</a>	<a href="#">Safety Violation</a>	<a href="#">Harmful Impurities</a>	<a href="#">Penetration Enhancer</a>	<a href="#">Unassessed Ingredient*</a>	<a href="#">Allergen &amp; Other Health Concerns</a>
						✓

### Explanation of Score

#### Health Concern

Present(s) safety concerns leading to cosmetic industry safety panel recommending limitations on concentration or use

### Government & Industry Toxicity Category Explanation

**CIR Category 1:** Safe as used. [CIR 2003]

**CIR Category 11:** Max "as used" concentration is basis of safety assessment. [CIR 2003]

**CIR Category 38:** Product type restrictions or differences noted. [CIR 2003]

### Product Categories with Dimethicone

Dimethicone is found in 1,689 product(s) in our database.

Product Category	Products Count
<a href="#">Moisturizer</a>	264
<a href="#">Foundation</a>	150
<a href="#">Eye Makeup</a>	131
<a href="#">Facial Moisturizer/Treatment</a>	92
<a href="#">Anti-Aging Treatment</a>	91
<a href="#">Mascara</a>	89

<u>Antiperspirant/Deodorant</u>	86
<u>Conditioner</u>	85
<u>Powder</u>	77
<u>Blush</u>	62
<u>Sunscreen/Tanning Oil</u>	59
<u>Lip Makeup</u>	52
<u>Shampoo</u>	51
<u>Concealer</u>	43
<u>Styling Product</u>	33
<u>Eye Treatment</u>	24
<u>Acne Treatment/Medication</u>	24
<u>Foot Odor/Cream/Treatment</u>	22
<u>Facial Cleanser</u>	22
<u>Baby Lotion/Oil</u>	21
<u>Lip Balm/Treatment</u>	21
<u>Hair Dye</u>	18
<u>Shaving Products</u>	17
<u>Exfoliator</u>	8
<u>Eye/Contact Care Product</u>	8
<u>Hair Spray</u>	8
<u>Skin Coloring</u>	8
<u>Anti-Itch/Rash Cream</u>	6
<u>Hair Relaxer</u>	4
<u>Depilatory Cream/Hair Remover</u>	4
<u>Body Wash/Cleansers</u>	4
<u>Other Skin Treatment</u>	4
<u>Mousse</u>	3
<u>Liquid Hand Soap</u>	3
<u>Body Oils</u>	2
<u>After Sun Product</u>	2
<u>Deodorant</u>	2
<u>Nail Treatments</u>	1
<u>Tooth Whitening</u>	1
<u>Pain Relief Rub/Ointment</u>	1
<u>Baby Bath Wash</u>	1
<u>Hair Regrowth Treatment</u>	1



## Listed on Packages As

Dimethicone  
 Simethicone  
 Dimethicone (in an anti-perspirant base of)  
 Dimethicone 1.5%  
 Dimethicone (5 %)  
 Dimethicone (2%)  
 Dimethicone (1%)  
 Dimethicone (and) Dimethiconol  
 Dimethicone 1%  
 Dimethicone 3%  
 Dimethicone 1.0%  
 Dimethicone (1%)(diaper rash cream)  
 Dimethicone and Dimethiconol  
 Dimethicone (5%)  
 Dimethicone (silica; derived from natural sources)  
 Dimethicone 2%  
 Dimethicone (Silica Derived)  
 Dimethicone (1%) (Skin Protectant)  
 Cyclomethicone & Dimethicone  
 Dimethicone (Silica)\*  
 Dimethicone (2% - Skin Protectant)  
 Dimethicone 1% (Diaper Rash Cream)  
 Dimethicone (2.0% Skin Protectant)  
 Dimethicone 1% (Skin Protectant)  
 Dimethicone (Silica)  
 Dimethicone+  
 Dimethicone 1.25% (Skin Protectant)  
 Dimethicone 1.25%  
 Dimethicone 2.0% (w/w) (Skin protectant)  
 Dimethicone 2% (w/w) (Skin Protectant)  
 Dimethicone (\*Silica)  
 Dimethicone (from Silica)

## References

[CIR 2003]: Cosmetics Ingredient Review (CIR) (2003). 2003 CIR Compendium, containing abstracts, discussions, and conclusions of CIR cosmetic ingredient safety assessments. Washington DC.

\* Ingredient(s) has/have not been assessed for safety by the cosmetic industry safety panel (the Cosmetic Ingredient Review, or CIR, panel) or by the federal government, with respect to use in cosmetics. Generally, ingredients not yet assessed for safety in cosmetics encompass a broad range of uses and toxicities - some are approved food additives while others are industrial chemicals linked to cancer. Some are generally known to be safe; others are linked to serious health concerns. More than 9,000 cosmetic ingredients have not been assessed for safety with respect to their use in these products.

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